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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,250	06/01/2001	Gary S. Grubb	AM100058	4735
35139	7590	09/14/2005	EXAMINER	
COZEN O' CONNOR, P. C.			HUI, SAN MING R	
1900 MARKET STREET			ART UNIT	
PHILADELPHIA, PA 19103-3508			PAPER NUMBER	

1617

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/872,250	Applicant(s) GRUBB, GARY S.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.  
 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-11 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Applicant's amendments filed May 31, 2005. Claims 1-11 are pending.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Endrikat et al., Hodgen et al. (US Patent 5,552,394) and Katzung, Endrikat et al. in view of Katzung are of record.

Endrikat et al. teaches oral contraceptives with 30mcg Ethinylestradiol has less breakthrough bleeding than that with 20mcg Ethinylestradiol in the first three cycles. Endrikat also teaches that the patterns of the breakthrough pain as highest in the first cycle was due to the fact that the adaptation of the endometrium to the exogenous hormones takes some time (See page 136, col. 1, last paragraph).

Hodgen et al. teaches a method of reducing breakthrough bleeding in the menstrual cycles except for the first cycle employing ultra-low dose of Ethinylestradiol. Hodgen et al. teaches the dose of Ethinylestradiol as 3-35 mcg (See for example the abstract, claims 1-12).

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The primary references do not expressly teach the combination of the oral contraceptives packs together in a kit. The primary references do not expressly teach all of the herein claimed progestins.

Katzung teaches the various progestins herein claimed as useful in oral contraceptive.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ various progestin herein claimed into the oral contraceptives.

One of ordinary skill in the art would have been motivated to combine the oral contraceptives packs of 30mcg and 20mcg of Ethinylestradiol together in a kit. Hodgen's method of reducing breakthrough bleeding has one drawback, which cannot reducing the breakthrough bleeding in the first cycle. Possessing the teachings of Endrikat, one of ordinary skill in the art would reasonably expect to employ a regimen comprising a dose of 30mcg of ethinylestradiol in the first cycle in the Hodgen's method in order to let the endometrium adapt to the exogenous hormones as well as reduce the breakthrough bleeding in the first cycle and thereby improving Hodgen's method.

One of ordinary skill in the art would have been motivated to employ various progestin herein claimed into the oral contraceptives since substituting various known progestin in oral contraceptives would be considered selecting obvious alternatives among known progestins, absent evidence to the contrary.

***Response to Arguments***

Applicant's arguments filed May 31, 2005 averring the teaching away by Endrikat et al. have been considered, but are not found persuasive. Taking the teachings of both Endrikat and Hodgen together, one of ordinary skill in the art would have realized the drawback for Hodgen's ultra low-dose estrogen method of contraceptives and the initial high dose of estrogen would reduce the incidence of unwanted bleeding taught in Endrikat. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to improve the contraceptive regimen for reducing side effects by increasing the initial dosage of estrogen and then subsequently reducing the dose. Furthermore, teaching away has to be positive. Endrikat does not discourage the use of relatively high dose of estrogen in the initial phase. There is no teaching away present in the cited prior art.

Applicant's arguments filed May 31, 2005 averring the lack of motivation provided by the cited prior arts have been considered, but are not found persuasive. As discussed above, the motivation to combine the teachings of cited prior arts is provided. Possessing the teachings of both Endrikat and Hodgen, one of ordinary skill in the art would have realized the drawback for Hodgen's ultra low-dose estrogen method of contraceptives and the initial high dose of estrogen would reduce the incidence of unwanted bleeding taught in Endrikat. Therefore, possessing the teachings of the cited prior arts, one of ordinary skill in the art would have been motivated to improve the contraceptive regimen for reducing side effects by increasing the initial dosage of estrogen and then subsequently reducing the dose.

Applicant's arguments filed May 31, 2005 averring hindsight reasoning being employed by the examiner have been considered, but are not found persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the motivation to combine the teachings of the cited prior arts is provided by the cited prior arts. Therefore, the claims are considered properly rejected under 35 USC 103(a).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

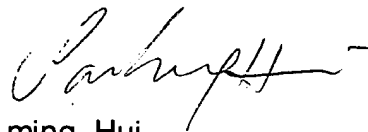
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



San-ming Hui  
Primary Examiner  
Art Unit 1617